DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 758-7132
FAX: (612) 334-4142

December 27, 2006

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 07 - 08

James and Gregory Rickert
Owners
Rickland Farms, LLC
W9135 Lincoln Road
Eldorado, Wisconsin 54932

Dear Messrs. Rickert:

An investigation of your dairy operation located at Lincoln Road, Eldorado, Wisconsin, conducted by a representative of the U.S. Food and Drug Administration (FDA), on September 12, 13, 20, and 26, 2006, confirmed that you offered an animal for sale for slaughter as food that was adulterated under sections 402(a)(2)(C)(ii) [21 U.S.C. 342(a)(2)(C)(ii)] and 402(a)(4) [21 U.S.C. 342(a)(4)] of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also revealed that you caused the new animal drugs sulfadimethoxine, neomycin, and spectinomycin to become adulterated within the meaning of section 501(a)(5) [21 U.S.C. 351(a)(5)] and unsafe under section 512 [21 U.S.C. 360b] of the Act. You can find the Act and its associated regulations on the Internet through links on the FDA's web page at www.fda.gov.

On or about August 4, 2006, you consigned [redacted], a cattle trucker, to transport a dairy cow identified with your farm ear tag 1416, for slaughter as food. [redacted] applied back tag 005 to this cow, and delivered the cow to [redacted], where it was slaughtered on or about August 4, 2006. USDA/FSIS analysis of tissue samples collected from that animal identified the presence of 0.64 ppm sulfadimethoxine in muscle tissue and 0.74 ppm sulfadimethoxine in liver tissue.

A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in uncooked edible tissues of cattle as codified in Title 21, Code of Federal Regulations, Part 556.640 (21 CFR 556.640). The presence of this drug in muscle and liver tissue from this animal in this amount causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) [21 U.S.C. 342(a)(2)(C)(ii)] of the Act.

Our investigation also found that you hold animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are

likely to enter the food supply. You lack an adequate system to ensure that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. For example, your firm's animal treatment records do not include the dosage given, route of administration, and appropriate withdrawal times for milk and meat. Food from animals held under such conditions is adulterated within the meaning of section 402(a)(4) [21 U.S.C. 342(a)(4)] of the Act.

In addition, you adulterated sulfadimethoxine, spectinomycin, and neomycin sulfate within the meaning of section 501(a)(5) [21 U.S.C. 351(a)(5)] of the Act when you failed to use these drugs in conformance with the approved labeling. "Extralabel use," i.e., the actual or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling, is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship. The extralabel use of approved veterinary or human drugs must comply with sections 512(a)(4) and 512(a)(5) [21 U.S.C. 360b(a)(4) and 21 U.S.C. 360b(a)(5)] of the Act and 21 CFR 530. Our investigation found that your extralabel use of sulfadimethoxine, spectinomycin, and neomycin sulfate failed to comply with these requirements.

For example, you administered sulfadimethoxine oral suspension intravenously to lactating dairy cows, which is not in accordance with the drug's approved labeling. Sulfadimethoxine is prohibited from extralabel use in lactating dairy cattle and your administration of this drug was in violation of 21 CFR 530.41(a)(9). Furthermore, your extralabel use resulted in an illegal drug residue, in violation of 21 CFR 530.11(d). In addition, you administered spectinomycin sulfate and neomycin sulfate to animals contrary to approved labeling and you did so without the supervision of a licensed veterinarian, in violation of 21 CFR 530.11(a). Neomycin and spectinomycin are not approved for use in female dairy cattle 20 months of age or older. Because your extralabel use of these drugs was not in compliance with 21 CFR Part 530, the drugs were unsafe under section 512(a) [21 U.S.C. 360b(a)] of the Act and your use caused the drugs to be adulterated within the meaning of section 501(a)(5) [21 U.S.C. 351(a)(5)] of the Act.

The above is not intended to be an all inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the food you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within fifteen (15) working days of receiving this letter. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include

copies of any available documentation demonstrating that corrections have been made.

Your written response should be sent to Marie A. Fadden, Acting Compliance Officer, U.S. Food and Drug Administration at the address located on the letterhead. If you have any questions about this letter, please contact Ms. Fadden at (612) 758-7172.

Sincerely,

W. Charles Becoat

W. Charles Becoat
Director
Minneapolis District

MAF/ccl

cc: Dr. Julie Cornett
USDA-FSIS Technical Service Center
Landmark Center, Suite 300
1299 Farnam Street
Omaha, NE 68102